

AP3 Rec'd PCT/PTO 03 JUN 2005

ENDOSCOPIC SURGERY DEVICE FOR THE INSERTION AND RECOVERY  
OF A HAEMOSTATIC PLUG AT THE SURGICAL SITE

DESCRIPTION

5       Field of the Invention

The present invention relates generally to the field of surgical instruments intended for use mainly, but not exclusively, for endoscopic surgery (laparoscopy, thoracoscopy etc.), including hand-assisted laparoscopy. 10 More specifically the invention relates to a device for the insertion and the recovery of a plug at the surgical site which can be used during surgery performed by endoscopic procedure.

Background of the Invention

15       In endoscopic surgery, a minimally invasive access to a cavity of the body, such as the abdominal cavity, is performed through the use of miniaturized optical and surgical instruments. In the case, for example, of the laparoscopic surgery, wherein the peritoneal cavity is 20 involved, this cavity is virtual under physiological conditions and cannot be explored by optical instruments. In order to make it real, its wall is raised by insufflating gas, generally CO<sub>2</sub>, to form a gas chamber, known as pneumoperitoneum. Access to the pneumoperitoneal 25 chamber is established by means of trocars fitted with a valve, so that communication between the interior and exterior of the abdomen takes place without a significant variation of the actual gas pressure. The surgical instruments are inserted through the trocars and the 30 optics connected externally to a TV camera connected to a monitor, in this way forming a take and image transmission system.

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Even if the pressure exerted on organs by the pneumoperitoneum facilitates spontaneous haemostasis of the countless capillaries which are lesioned, it is however essential that perfect haemostasis be performed straightway, otherwise visibility is reduced until it is impossible, and in any case unadvisable, to continue the operation by the laparoscopic procedure without the necessary safety. Normally, in this type of operation, the outflowing blood and liquids are aspirated to keep the surgical site clean and ensure adequate instrumental visibility. However implementation of aspiration is not wholly efficient and can only be put into use after a few moments, which is often decisive. The use of absorbent plugs inserted in the surgical site by means of a forceps through a trocar is equally inefficient.

US patent no. 5,310,407 discloses an instrument for the insertion of a haemostatic plug in the abdominal cavity in a laparoscopic procedure formed by a tubular element wherein a plug of haemostatic material is placed and a sliding plunger for applying the plug directly where bleeding has occurred.

The disadvantage of the device described above, as well as in the case of the insertion of a plug by means of a forceps through a trocar, lies in the fact that the recovery of the plug by means of a forceps may be laborious and even dangerous, especially in the case of a laparoscopic surgical operation for the removal of a tumour. In this case the dissemination of cells, including cancerous cells, due to the partial squeezing of the plug during its passage through the trocar, may take place at a site far from that where the tumour developed and may therefore give rise to very serious remote neoplastic

dissemination which is difficult to treat. There is also a definite risk of "forgetting" the plug introduced into the body cavity or in any case it may be difficult to find it again for removal when it is soaked with blood or other bodily fluids. This "oversight" is a frequent source of medical and legal disputes and, albeit less frequent in laparoscopic surgery compared to "open" surgery, constitutes in any case a not negligible risk.

Object and summary of the Invention

10       The object of the present invention is to provide a device for the removal of organic fluids from a body cavity during an endoscopic operation capable of overcoming the various drawbacks discussed above.

15       A particular object of the invention is to provide a device for the insertion of an absorbing plug in an abdominal cavity during a laparoscopic surgical operation which also allows safe and easy location of the plug, thus facilitating its recovery after use and in this way avoiding the risk of losing the plug in the surgical site, and leaving it in the patient body, and also  
20       avoiding possible cells dissemination in areas far from the surgical site.

25       Another object of the invention is to provide an haemostatic plug which can easily be retrieved and recovered after use.

30       These objects are achieved with the device for the removal of organic fluids from a body cavity during an endoscopic operation according to the present invention whose feature consists in that it comprises an absorbing plug and a tubular body, suitable for slidably housing the plug, and a plunger which can be engaged slidably inside the tubular body to push the plug outside thereof

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at the surgical site, said plug being connected to plug location means comprising a radio-opaque body floating on the internal organs, blood or other liquids present at the surgical site, means for gripping said location means  
5 being provided at the distal end of the plunger for recovering the plug and withdrawing it inside the tubular body.

Brief description of the drawings

Further features and advantages of the endoscopic  
10 surgery device according to the present invention will be made clearer by the following description of one of its embodiments, given by way of a non-limiting example with reference to the accompanying drawings, wherein:

- Figure 1 is a perspective view of the device  
15 according to the invention, some parts of it being removed for clarity of illustration;
- Figure 2 is an exploded perspective view of the device of Figure 1;
- Figure 3 is a detailed view of the end portion of  
20 the plunger;
- Figures 4a, 4b and 4c illustrate the steps of recovery of the plug with the device of Figure 1.

Referring to Figures 1 and 2, 1 denotes a rigid tubular sheath with open distal and proximal ends,  
25 indicated at 1a and 1b respectively. The proximal portion of the tubular sheath 1 is engaged firmly in a hub 2 provided with handle means in the form of two diametrically opposite annular grips 3a, 3b co-planar to the sheath 1.

30 A stem 4 is slidably inserted in the tubular sheath 1 whose distal end 4a has an eyelet configuration made, in the present embodiment of the invention, with a flexible

thin plate 5 bent in two in such a way as to form a loop with its ends connected to the end 4a of the stem 4 via a transverse peg 6 (Figure 3). Advantageously the thin plate 5 may be a strip of rectangular section and may be made of harmonic or nickel-titanium steel, in such a way as to exhibit sufficient flexural rigidity. The proximal end 4b of the stem 4 ends with an annular grip 7, in the present embodiment, connected by a steel peg, not shown, to the stem 4 and co-planar thereto.

10       The tubular sheath 1 and the stem 4 are preferably made of metal or of a plastic material suitable for surgical use, for example polyethylene, Teflon and the like. The annular grips 3a, b and 7 are made of a similar material. Circumferential grooves 11 are advantageously  
15       provided along the stem 4 for housing O-rings, not shown, suitable for facilitating sliding along the internal lubricated surface of the tubular sheath 1.

          The device according to the invention also comprises an absorbent plug 8 which has an elongated shape, in  
20       particular it is substantially pear-shaped, its shape being suitable for allowing it to be inserted in the tubular sheath 1. The plug 8 is connected by a wire 9 to a ball 10 with lower specific weight than that of blood, and therefore floating in relation thereto, and radio-opaque  
25       so as to be visible to X rays. The ball 10 should preferably be coloured so as to be visually identifiable within the surgical field and must have a surface finish such as to allow sliding of blood over its surface. The plug 8 can be made of any material suitable for  
30       haemostasis and absorption of blood and any other liquid which may be present in the surgical field. Advantageously it may be made of polyvinyl alcohol (PVA) as in the

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products available under the commercial names Meracel® or Ivalon® or other equivalent products.

The wire 9 is made of a biocompatible material, for example suture thread, with diameter of 0.5 mm and length  
5 of 8-10 cm.

The dimensions of the ball 10 are such as to allow its insertion in the tubular sheath 1 and, in turn, determine the dimension of the loop formed at the end 4a of the stem 4 which has to be slightly larger than that of  
10 the body 10. Said ball must also be white in colour (or yellow, or in any case a light colour) so as to be easily identified at the surgical site, and also radio-opaque. More than one of said balls may also be provided.

The length of the stem 4 is greater or at most equal  
15 to that of the tubular sheath 1 to ensure that the eyelet end 4a of the stem 4 projects fully from the tubular sheath 1 when the stem 4 is fully inserted in said sheath.

In order to drive the plug to the surgical site, the abdominal cavity is reached through a trocar by  
20 introducing therein the tubular sheath 1 of the inserting device wherein a plug 8 has previously been placed. By sliding the stem 4, which acts as a plunger, the plug 8 is pushed outside of the tubular sheath 1 and positioned by the surgeon in the place of use.

25 Once the plug 8 has performed its function, it has to be recovered and taken outside of the abdominal cavity. For this purpose, as shown in Figures 4a, b and c, the ball 10 is identified visually and the eyelet end 4a of the stem 4 is moved towards it, to get the ball to pass  
30 through the loop so as to hook the wire 9 of the plug 8. The loop is then made to slide along the wire with light hand movements and the stem 4 is pulled backwards, in the

direction of arrow F in Figure 4c, until the plug has returned fully inside the tubular sheath 1, after which the device is disengaged from the trocar.

The advantage obtained with the use of the device according to the present invention consists in that the operation of recovery of the plug, and in particular its reinsertion in the tubular sheath 1 after use, is performed directly at the surgical site, so that the inevitable partial squeezing of the plug is not a source of remote contamination, particularly dangerous in the presence of tumoral cells due to the possibility of neoplastic dissemination with the risk of the formation of metastasis. The partial squeezing of the plug in the surgical site gives rise, in the worst hypothesis, to a microscopically incomplete removal of the tumour, moreover inevitable with or without the plug, which will give rise possibly to a local relapse of the disease, always preferable to remote metastasis.

The loop hooking device described above is currently considered preferred due to its simplicity and effectiveness. It is moreover evident that equivalent hooking devices, which may be suggested to a person skilled in the art on reading this description, are to be considered as coming within the scope of this invention.

Various modifications and alteration to the invention may be appreciated based on a review of the disclosure. These changes and additions are intended to be within the scope and spirit of the invention as defined by the following claims.

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CLAIMS

1. An endoscopic surgery device for the removal of organic fluids from a body cavity, comprising an absorbing plug (8) and a tubular body (1), suitable for slidably housing said plug (8), and a plunger (4) slidably engageable in said tubular body to push said plug outside thereof and place it at the surgical site, said tubular body (1) and plunger (4) having distal ends (1a, 4a) and proximal end (1b, 4b), characterised in that said plug is connected to plug radio-opaque location means (9,10) floating in relation to the internal organs, blood or other liquids present at the surgical site, and that at the distal end (4a) of said plunger (4) means (5) are provided for gripping said location means to recover said plug after use by retracting it inside said tubular body.
2. Device according to claim 1, wherein said location means comprise at least one ball (10) of lower specific weight than that of the internal organs, blood or other liquid present at the surgical site, connected to said plug (8) by a wire (9).
3. Device according to claim 2, wherein said at least one ball (10) has smaller dimensions than the internal ones of said tubular body (1).
4. Device according to any one of the previous claims, wherein said plunger comprises a stem (4) and said gripping means comprises a loop (5) at the distal end (4a) of said stem (4), said loop being wider than said ball (10).
5. Device according to claim 4, wherein said loop (5) is formed by a thin plate bent and connected by its ends to the distal end of said stem.
6. Device according to any one of the previous claims,



wherein at the proximal ends (1b, 4b) of said tubular body (1) and of said stem (4) handle means (3a, 3b, 7) are provided for actuating axial sliding of said stem in one direction or the other as a result of corresponding pressure actions exerted simultaneously in opposite directions on said handle means.

7. Device according to claim 6, wherein said handle means are of the ring type to allow engaging of the fingers of a user.

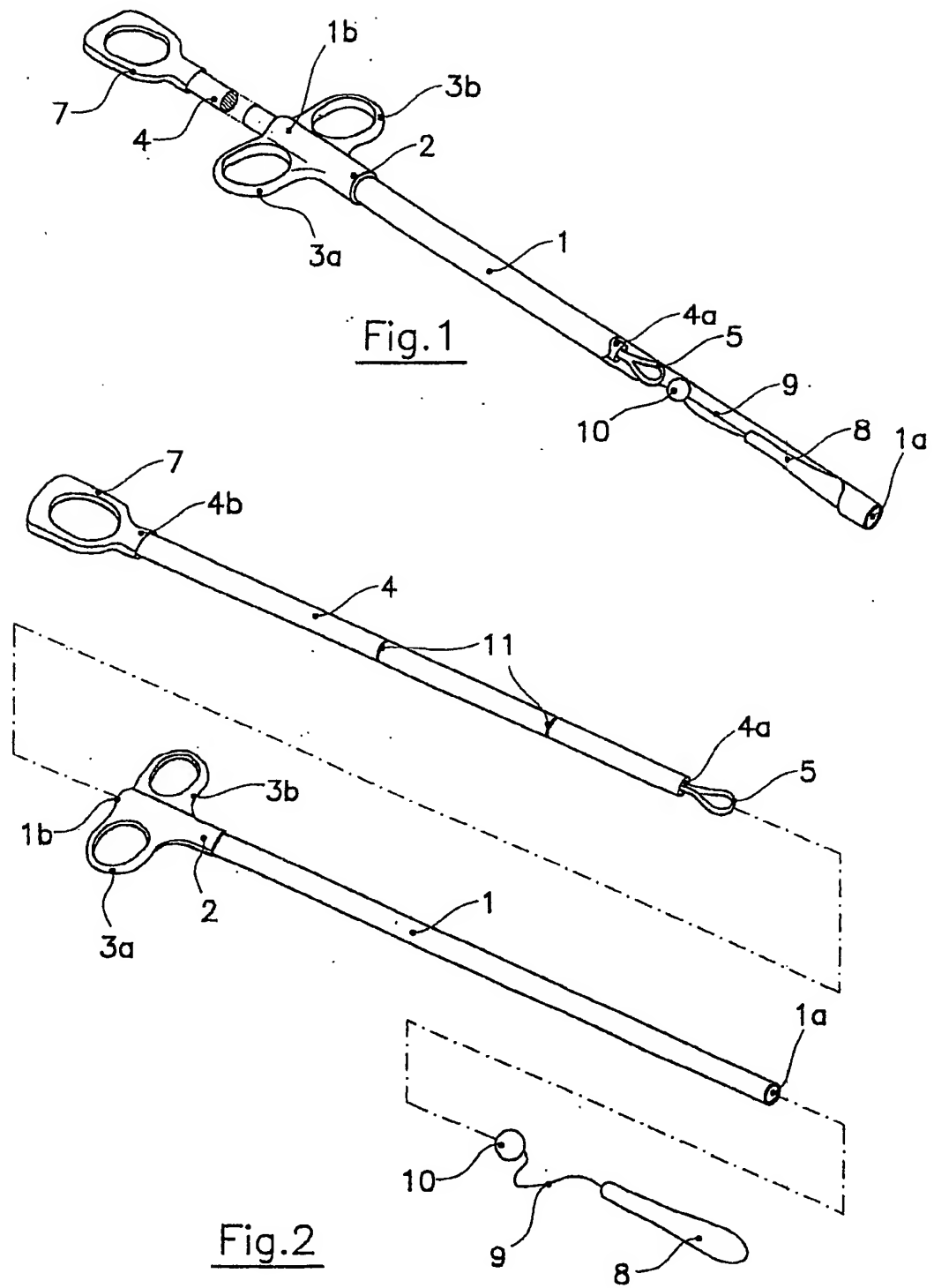
8. Device according to claim 7, wherein at the proximal end (1b) of said tubular body (1) a pair of handle rings (3a, 3b) are provided, diametrically opposite and co-planar thereto, while at the proximal end (4b) of said stem (4) an handle ring (7) is provided, co-planar thereto.

9. Device according to any one of the previous claims, wherein the ball surface is white or coloured with a light colour.

10. Organic liquid absorbing plug for surgical use comprising an elongated body in a material with absorbent and haemostatic properties and characterised in that said body is connected to plug radio-opaque location means (9, 10), floating in relation to the internal organs, blood or other liquids present at the surgical site.

11. Organic liquid absorbing plug according to claim 10, wherein said location means comprise at least one ball (10) with lower specific weight than that of internal organs, blood or another liquid present at the surgical site, connected to said plug by a wire (9).

12. Organic liquid absorbing plug according to claim 10 or 11, wherein the ball surface is white or coloured with a light colour.



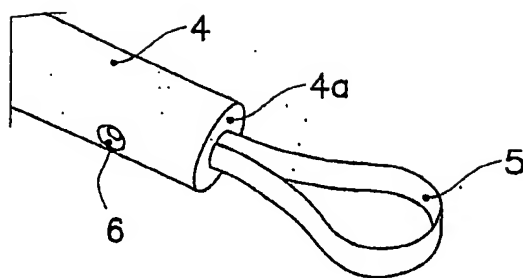


Fig. 3

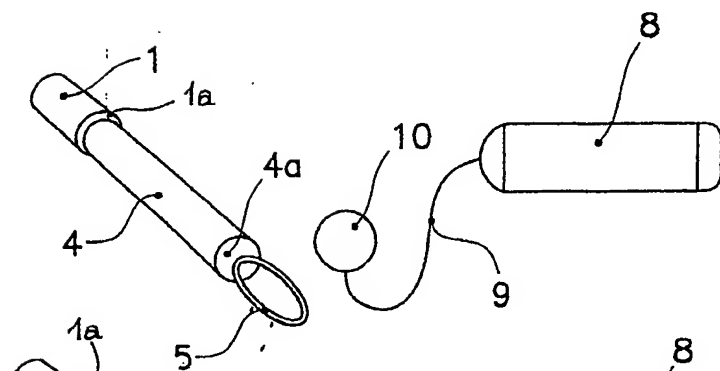


Fig. 4a

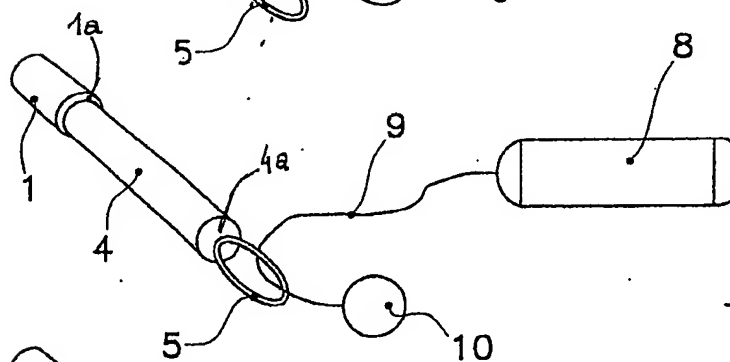


Fig. 4b

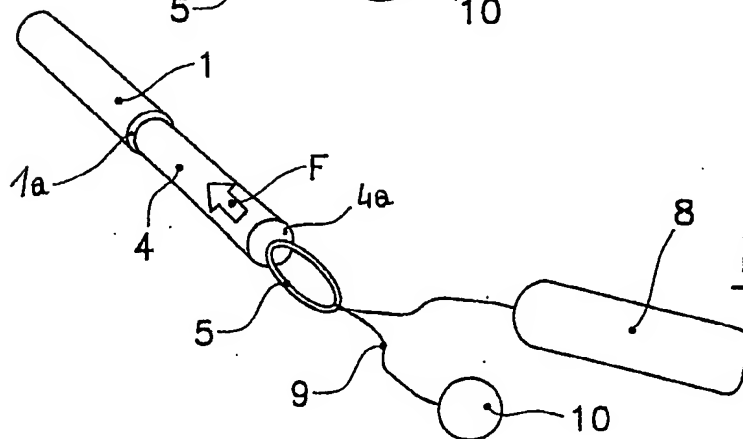


Fig. 4c

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC 7 A61F13/36

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

 Minimum documentation searched (classification system followed by classification symbols)  
 IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 203 767 A (CLOYD ET AL) 20 April 1993 (1993-04-20) column 2, line 51 - column 3, line 4	1,6,7
Y		10
Y	US 5 074 840 A (YOON ET AL) 24 December 1991 (1991-12-24) column 3, line 61 - line 65	10
A	US 5 447 499 A (ALLAIRE ET AL) 5 September 1995 (1995-09-05) the whole document	1
Y	US 5 310 407 A (CASALE ET AL) 10 May 1994 (1994-05-10) cited in the application column 3, line 44 - line 46	10
	-/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

## \* Special categories of cited documents :

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Date of the actual completion of the international search

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# INTERNATIONAL SEARCH REPORT

Inter  al Application No  
PCT/IT2004/000643

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3 698 393 A (CHARLES E. STONE) 17 October 1972 (1972-10-17) the whole document	10
Y	US 6 191 341 B1 (SHIPPERT RONALD D) 20 February 2001 (2001-02-20) column 8, line 24 - line 27	10
Y	US 2003/073969 A1 (KLAINER PETER S) 17 April 2003 (2003-04-17) figure 2	10

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5203767	A	20-04-1993	NONE		
US 5074840	A	24-12-1991	AT	173912 T	15-12-1998
			AU	689397 B2	26-03-1998
			AU	1002597 A	27-02-1997
			AU	699523 B2	03-12-1998
			AU	5286298 A	21-05-1998
			AU	672722 B2	10-10-1996
			AU	7762894 A	12-01-1995
			AU	667787 B2	04-04-1996
			AU	7762994 A	12-01-1995
			AU	676383 B2	06-03-1997
			AU	7763094 A	12-01-1995
			AU	651843 B2	04-08-1994
			AU	8445191 A	18-02-1992
			CA	2088070 A1	25-01-1992
			DE	69130567 D1	14-01-1999
			DE	69130567 T2	12-05-1999
			EP	0540682 A1	12-05-1993
			ES	2125238 T3	01-03-1999
			JP	5509024 T	16-12-1993
			KR	9604969 B1	18-04-1996
			US	5451204 A	19-09-1995
			US	6277089 B1	21-08-2001
			WO	9201433 A1	06-02-1992
			US	5827215 A	27-10-1998
			US	6248088 B1	19-06-2001
			US	5484426 A	16-01-1996
			US	5392787 A	28-02-1995
			US	5514085 A	07-05-1996
			US	5439457 A	08-08-1995
			US	5556376 A	17-09-1996
			US	5407423 A	18-04-1995
			US	5599292 A	04-02-1997
			US	5649902 A	22-07-1997
			US	5755724 A	26-05-1998
			US	5733252 A	31-03-1998
			US	5374261 A	20-12-1994
			US	5700239 A	23-12-1997
			US	5843017 A	01-12-1998
			US	2001025155 A1	27-09-2001
			US	5836953 A	17-11-1998
US 5447499	A	05-09-1995	AU	651286 B1	14-07-1994
			CA	2109981 A1	24-06-1994
			EP	0604101 A1	29-06-1994
			JP	6233810 A	23-08-1994
			NZ	250214 A	26-10-1995
			ZA	9308595 A	05-08-1994
US 5310407	A	10-05-1994	NONE		
US 3698393	A	17-10-1972	NONE		
US 6191341	B1	20-02-2001	AU	3648999 A	08-11-1999
			WO	9953879 A1	28-10-1999
US 2003073969	A1	17-04-2003	NONE		